JAN 30 2012

Section C.

510(k) Summary

Date Prepared: December 12, 2011

1. 510(k) Summary of the safety and effectiveness of Aldahol® V High Level Disinfectant (K113015), a liquid chemical high level disinfectant and sterilant.

a. Applicant/Sponsor

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c. Name of the device

Trade Name: Aldahol® V High Level Disinfectant
Common Name: Liquid Chemical Sterilant and High Level Disinfectant
Classification Name: Liquid chemical sterilants/high level disinfectants (21 CFR 880.6885)
Classification: Class II

d. Predicate Name

Aldahol® III High Level Disinfectant (K041360)

e. Summary of the substantial equivalence (SE) of Aldahol V High Level Disinfectant to the predicate, Aldahol III High Level Disinfectant (K041360)

Aldahol V High Level Disinfectant (HLD) is exactly the same formulation as the predicate, Aldahol III High Level Disinfectant (HLD) (K041360), which has been in commercial use now since 2010. Both Aldahol V HLD, and the predicate, Aldahol III HLD, are high level disinfectants with an exposure of 10.0 min at 20°C, and sterilants with an exposure of 8.0 and 10.0 hrs respectively at 20°C. The difference between them is the minimum recommended concentration (MRC) of glutaraldehyde, which is 1.8% w/w glutaraldehyde for Aldahol V HLD, and 2.1% w/w glutaraldehyde for Aldahol III HLD predicate. This difference is important to maximize the number of endoscope reprocessing cycles available from the disinfectant, and thus minimize the cost of high level disinfection per endoscope, and prevent the waste of disinfectant. Both Aldahol V HLD and the predicate, Aldahol III HLD, are formulated with 3.4% ± 0.2% w/w glutaraldehyde as the active ingredient supplemented with 20.1% ± 1% w/w isopropanol. The pH values for the unactivated Aldahol V HLD and the predicate are 6.5 to 6.8, and both the Aldahol V HLD and the predicate are activated at the time of use with a trisodium phosphate liquid activator solution to activated pH values of 7.6 to 7.9. In response to questions from customers, we tested Aldahol V HLD also at pH 8.5 against *M. terrae* and *B. subtilis* in rate-of-kill tests, and found that Aldahol V HLD also meets its antimicrobial claims at pH 8.5. Reports of these pH 8.5 tests are included in Section O, Non-Clinical Antimicrobial Activity Tests. Both Aldahol V HLD and the predicate, Aldahol III HLD, are to be used and re-used for 14 days or until the glutaraldehyde concentration declines to a minimum recommended concentration of 1.8% w/w glutaraldehyde and 2.1% glutaraldehyde, respectively, as monitored by legally marketed glutaraldehyde test strips or liquid indicator solutions.

f. Device Description

Aldahol V High Level Disinfectant (HLD) is an aqueous solution that requires the combination of two parts: the light yellow unactivated Aldahol V HLD solution, packaged in gallon-sized containers, and a red Activator Buffer Salt Solution packaged in twelve ounce containers.

Once activated, the red/red-orange Aldahol V HLD as initially manufactured contains 3.40 ± 0.2% w/w glutaraldehyde and 20.1% ± 1% w/w isopropanol in a buffered salt solution with a pH

value of about 7.6 to about 7.9, containing a surfactant, and potassium acetate salts all intended to enhance the antimicrobial activity of the solution. The glutaraldehyde concentration of both activated Aldahol V HLD, and the predicate activated Aldahol III HLD remains constant over a period of 14 days, declining only as the result of inadvertent dilution with rinse water during use and re-use.

The microbiocidal mode of action of glutaraldehyde has been extensively studied and reviewed since glutaraldehyde was introduced as a disinfectant in the late 1960's. All of these reviews indicate that glutaraldehyde cross-links proteins and lipoproteins of microbes to denature them thus killing the cells. Possibly the alcohol, salts, and surfactants help the glutaraldehyde to penetrate lipid cell membranes and other cell wall chemistry.

g. Intended Use

Aldahol® V High Level Disinfectant is intended for the high level disinfection of reusable, clean, heat-sensitive, semi-critical medical devices which contact intact mucous membranes when the disinfectant is used at or above its minimum recommended concentration of 1.8% glutaraldehyde for 10.0 min at 20°C.

Aldahol V High Level Disinfectant is intended for the sterilization of reusable, clean, heat-sensitive critical and semi-critical medical devices which contact and potentially penetrate into sterile body areas, for which there is no other practical method of sterilization available with a biological indicator, when the disinfectant is used at or above its minimum recommended concentration of 1.8% glutaraldehyde for 8.0 hrs at 20°C.

Aldahol V High Level Disinfectant may be used in a legally marketed, validated, automatic endoscope reprocessor machine or in a manual bucket system.

h. Technological Comparison to Predicate

Aldahol V HLD and the predicate, Aldahol III HLD, both have the same unactivated and activated formula, and both are glutaraldehyde-based disinfectants combined with isopropanol. The only differences in the two products are that Aldahol III HLD has an MRC of 2.1% w/w

glutaraldehyde, and is used at 20±1°C for high level disinfection in 10.0 minutes and sterilization in 10.0 hours, while Aldahol V HLD, has an MRC of 1.8% w/w glutaraldehyde and is used at 20±1°C for high level disinfection in 10.0 minutes and sterilization in 8.0 hours. The formulation, packaging, unactivated and activated chemical stability, materials compatibility, and toxicity of Aldahol V HLD, and the predicate Aldahol III HLD are identical because the chemical formulations are identical. The shorter sterilization exposure time of 8.0 hrs for Aldahol V versus 10.0 hrs for Aldahol III is a result of testing Aldahol V at shorter exposure times.

i. Non-clinical Efficacy Testing

The following antimicrobial efficacy testing used Aldahol V HLD with the following conditions: Aldahol V HLD was stressed in an Environmental Protection Agency Use and Re-Use Test to the end of the 14-day reuse period, and then further diluted with synthetic hard water to 1.8% w/w glutaraldehyde. The testing validated that Aldahol V HLD was bactericidal, tuberculocidal, virucidal, fungicidal, and sporicidal according to standard test methods.

The bacteria *Staphylococcus aureus*, *Salmonella choleraesuis,* and *Pseudomonas aeruginosa* were killed with exposure for 10.0 minutes at 18°C to Aldahol V HLD per the AOAC Use-Dilution Tests. The fungi *Trichophyton mentagrophytes, Aspergillus niger,* and *Candida albicans* were killed with exposure for 5.0 minutes at 18°C to Aldahol V HLD per the AOAC Fungicidal Test. Greater than 6 $\log_{10}$ of the mycobacterium *Mycobacterium terrae* were killed within 10.0 minutes at 20°C. The viruses Adenovirus Type 2, Herpes Simplex Virus Type 1, Human Influenza Virus A, and Poliovirus Type 1 were killed within the limits of detection with exposure for 10.0 minutes at 20°C to Aldahol V HLD. *Bacillus subtilis* and *Clostridium sporogenes* inoculated porcelain penicylinders and silk suture loops were sterilized by Aldahol V HLD within 8.0 hours of exposure at 20°C per the AOAC Sporicidal Test.

In Simulated Use Tests, the interior channels and exterior surfaces of a bronchoscope, gastroscope, and colonoscope were inoculated with cultures of *M. terrae* and high level disinfected with Aldahol V HLD with 10.0 minutes exposure at 20°C, killing > 6 $\log_{10}$ of these mycobacteria. In a similar study, a bronchoscope, gastroscope, and colonoscope were inoculated

with cultures of *B. subtilis* and sterilized with Aldahol V HLD within 6.0 hours exposure at 20°C, killing > 6 $\log_{10}$, demonstrating a margin of safety for the 8.0 hour sterilization time. The results of these tests validate that Aldahol V HLD has efficacy as a high level disinfectant and sterilant on actual devices.

Simulated Use Tests conducted by Olympus Medical Systems Corporation in Tokyo, Japan tested *M. terrae*-inoculated colonoscopes in the OER-Pro automated endoscope reprocessing machine. In these studies, Aldahol killed > 6 $\log_{10}$ of *M. terrae* within a 10 minute disinfection cycle at ambient temperature.

j. Clinical Efficacy Testing

Bronchoscopes, gastroscopes and colonoscopes as received directly from patients at an endoscopy department within a hospital, and cleaned, but not disinfected, according to standard cleaning procedures of the department, were exposed for 10.0 minutes at 20°C to worst-case Aldahol V HLD from a 14-day EPA Reuse Test, further diluted to 1.8% w/w glutaraldehyde. No (zero) bacteria were recovered from these endoscopes after the exposure to Aldahol V HLD.

k. Biocompatibility

Biocompatibility testing determined that residues of glutaraldehyde and isopropanol, both soluble in water, 60 g of glutaraldehyde per 100 g water, and infinite solubility for isopropanol in water, respectively, remaining on endoscopes after sterilization or high-level disinfection with Aldahol III HLD and rinsing with water with three separate rinses were below toxic concentrations for glutaraldehyde and isopropanol as reported in the literature. Aldahol III HLD and Aldahol V HLD have exactly the same formulations, exposure times and temperatures, except that the MRC of Aldahol V HLD is lower at 1.8% glutaraldehyde than the MRC of Aldahol III HLD at 2.1% glutaraldehyde. Chemical stability, toxicity, and materials compatibility data as developed for Aldahol III HLD were also used for Aldahol V HLD because the formulas and exposure times and temperatures are exactly the same.

l. Material Compatibility

Material compatibility testing demonstrated that Aldahol III HLD can be used with endoscopes and a variety of materials commonly used in medical facilities at 20°C. With the exception of brass and copper that showed changes after 7 hours, no compatibility issues were found. Aldahol V HLD is compatible with the materials and devices listed and used according to the Directions for Use. Aldahol V HLD is exactly the same activated formulation as the predicate, Aldahol III HLD, which has been in use with endoscopes since 2010, and the compatibility data as developed for Aldahol III HLD were also used for Aldahol V HLD.

m. Stability

Aldahol III HLD and the Activator Buffer Salt Solution were tested and both found to be stable at the labeled expiration date. The formulations for Aldahol V HLD and Aldahol III HLD are identical, and thus the stability data developed for Aldahol III HLD were also used for Aldahol V HLD. The warehouse/shelf-life/expiration date for Aldahol V HLD is 18 months post manufacture.

n. Test Strip

3M Comply 1.8% Glutaraldehyde Monitor Strips Catalog No. 3987 was able to measure the glutaraldehyde concentration of Aldahol V HLD at its MRC of 1.8% w/w glutaraldehyde or greater (the 3M Glutaraldehyde Monitor test strips labeled for 1.8% glutaraldehyde routinely fail at 2.3% or 2.4% glutaraldehyde) when used according to the Directions for Use. MetriTest 1.8% glutaraldehyde concentration monitor Reorder No. 10-304 may also be used to measure the glutaraldehyde concentration in activated Aldahol V HLD.

o. Substantial Equivalence Conclusion

Aldahol V HLD and the predicate, Aldahol III High-Level Disinfectant, have exactly the same unactivated and activated formula, and both are glutaraldehyde-based disinfectants combined with 20.1% w/w isopropanol.

Worst case Aldahol V HLD passed all of the *in vitro* antimicrobial tests with exposures of 10.0 min (or less) for high level disinfection, and the AOAC Sporicidal Test for sterilization within 8 hours, at 20° C at 1.8% glutaraldehyde, and passed the simulated use test in bronchoscopes, gastroscopes and colonoscopes within 10.0 min at 20°C at 1.8% glutaraldehyde. Worst case

Aldahol V HLD passed the clinical in-use test in gastroscopes, colonoscopes, and bronchoscopes within 10.0 minutes at 20°C at 1.8% glutaraldehyde.

Therefore we conclude that Aldahol V High Level Disinfectant is safe and effective, and substantially equivalent (SE) to the predicate, Aldahol III High-Level Disinfectant (K041360).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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JAN 3 0 2012

Re: K113015
Trade/Device Name: Aldahol® V High Level Disinfectant
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: December 28, 2011
Received: December 30, 2011

Dear Dr. Miner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

Section D.

Indications for Use

510(k) Number (if known): _____

Device Name: Aldahol® V High Level Disinfectant

Indications for Use:

Aldahol® V High Level Disinfectant is intended for the high level disinfection of reusable, clean, heat-sensitive, semi-critical medical devices which contact intact mucous membranes when the disinfectant is used at or above its minimum recommended concentration of 1.8% glutaraldehyde for 10.0 min at 20°C.

Aldahol V High Level Disinfectant is intended for the sterilization of reusable, clean, heat-sensitive critical and semi-critical medical devices which contact and potentially penetrate into sterile body areas, for which there is no other practical method of sterilization available with a biological indicator, when the disinfectant is used at or above its minimum recommended concentration of 1.8% glutaraldehyde for 8.0 hrs at 20°C.

Aldahol V High Level Disinfectant may be used in a legally marketed, validated, automatic endoscope reprocessor machine or in a manual bucket system.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth P. Claverie-Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113015